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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/590,375	06/09/2000	Keiji Endo	2173-0120P	2206

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EXAMINER	
SLOBODYANSKY, ELIZABETH	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/590,375	ENDO ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky, PhD	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-27 and 30-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *27* is/are allowed.

6)☒ Claim(s) *25,26,33-35,39-42 and 46* is/are rejected.

7)☒ Claim(s) *30-32,36-38,43-45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment field November 16, 2004 canceling claims 1, 3, 5, 6, 10, 12, 13, 15, 17-24, 28 and 29, amending claim 25 and adding claims 30-46 has been entered.

Claims 25-27 and 30-46 are pending.

Claim Objections

Claims 26 and 27 are objected to because of the following informalities: claims 26 and 27 are identified as "(Previously Presented –Allowed)". While there is a claim identifier "(Previously Presented)", there is no claim identifier "(Allowed)".

Claims 30-35, 43 and 45 are objected to because of the following informalities: claims 30-35, 43 and 45 recite "the substitution ... with another amino acid, respectively". Because "another amino acid" is not specified, "respectively" is not needed.

Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25, 26, 33-35 and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 25, with dependent claim 26, has been amended to include mutation at 107th Met. New claims 33-35 and 39-41 recite said mutation. Applicants indicate support for such amendment on page 25, lines 11-14 (Remarks of 11/16/04, page 9). However, the specification on page 25, lines 11-14, provides support for mutants having several mutations including M107L not a single mutation. The examiner is unable to locate adequate support in the specification for a single substitution at 107th Met either with Leu or with any amino acid. Thus, there is no indication that a mutant α-amylase obtained by introducing substitution at 107th Met either with Leu or with any amino acid was within the scope of the invention as conceived by Applicants at the time the application was filed.

Claim 42 is drawn to a mutant α-amylase obtained by introducing a mutation into SEQ ID NO:1, wherein said mutation consists of: the substitution of an amino acid residue selected from the group consisting of:167th Gln, 169th Tyr, 190th Asn, and 209th Gln with Glu, Lys, Phe, and Val, respectively, and the substitution of an amino terminal sequence from 1st Asp through 19th Gly of SEQ ID NO:1 with an amino acid sequence from 1st His to 21st Gly of SEQ ID NO:2. Therefore, claim 42 is drawn to a mutant α-amylase having a single mutation and a substitution of an amino terminal sequence. Applicants indicate support for claim 42 on page 27, Table 7 (Remarks, page 10). However, the specification on page 27, Table 7, provides support for a mutant α-amylase LA-K38AMY/Q167E/Y169K/N190F/Q209V, i.e. having all of the above

mutations. Thus, there is no indication that a mutant α-amylase obtained by introducing a mutation into SEQ ID NO:1, wherein said mutation consists of: the substitution of an amino acid residue selected from the group consisting of:167th Gln, 169th Tyr, 190th Asn, and 209th Gln with Glu, Lys, Phe, and Val, respectively, and the substitution of an amino terminal sequence from 1st Asp through 19th Gly of SEQ ID NO:1 with an amino acid sequence from 1st His to 21st Gly of SEQ ID NO:2 was within the scope of the invention as conceived by Applicants at the time the application was filed.

Accordingly, Applicants are required to cancel the new matter in the response to this Office Action.

Claims 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutant α-amylase obtained by a substitution at a single position selected from the group consisting of positions 11, 16, 49, 84, 144, 167, 169, 178, 188, 190, 205 and 209 in SEQ ID NO:1, does not reasonably provide enablement for a mutant α-amylase obtained by a substitution at "at least" said single position, i.e. at other positions as well. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

For the purposes of this rejection, claims 25 and 26 were construed as drawn to a mutant α-amylase comprising at least one specific mutation selected from the group selected consisting of 12 specific positions, wherein the total number of possible mutations is not limited.

Claims 25 and 26 are so broad as to encompass any mutant α-amylase of any structure comprising at least one specific mutation and an unknown number of any other mutations. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of mutant α-amylases broadly encompassed by the claims.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass mutant α-amylases comprising a single specific mutation with an unknown homology to SEQ ID NO: 1 because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting α -amylase activity; (B) the general tolerance of α-amylases to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any α-amylase residues with an expectation of obtaining any α-amylase activity or α-amylase activity combined with increased heat resistance and resistance to chelating agents and high specific activity;

and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of amino acid substitutions in SEQ ID NO:1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making a mutant α-amylase comprising a single specific substitution and having an unknown number of other substitutions in SEQ ID NO:1 is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is drawn to a mutation selected from the group of specific mutations and the substitution of an amino terminal sequence. Thus, claim 42 appears to be drawn to a single specific mutation and the substitution of an amino terminal sequence.

Thus, claim 42 is confusing as reciting "a mutation", i.e. a single mutation, wherein there are two types of changes to the sequence of SEQ ID NO:1. i.e., a single mutation and the substitution of an amino terminal sequence.

Claim 46 is confusing as dependent from claim 44 where it appears the dependence from claim 45 was intended. Claim 46 was construed as dependent from claim 45.

Allowable Subject Matter

Claim 27 is allowed.

Response to Arguments

Applicant's arguments filed November 16, 2004 have been fully considered but they are not persuasive.

Applicants argue that "claim 30 is directed to a mutant α-amylase obtained by substituting the 167th Gln and 169th Tyr of SEQ ID NO:1 with another amino acid" (Remarks, page 11, 1st paragraph, emphasis added). It appears that applicants mischaracterize claim 30 and similar claims. It is noted that claim 30 is directed to a mutant α-amylase obtained by substituting of an amino acid residue selected from the group consisting of: 167th Gln and 169th Tyr of SEQ ID NO:1 with another amino acid, i.e. to a mutant with a single mutation not two mutations. While the specification has support for two of the above mutations, the claim as written is directed to only one of two mutations.

Applicants argue that the outstanding rejections are moot in view of the cancellation of the claims (Remarks, pages 11-13). However, the amendment required the rejections discussed above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky, PhD whose telephone number is 571-272-0941. The examiner can normally be reached on M-F 10:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, PhD can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
Art Unit 1652

February 16, 2005